

Attorney Docket No.: DEX0477US.NP
Inventors: Macina et al.
Serial No.: 10/553,436
Filing Date: March 21, 2006
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REMARKS

Claims 1-6, 8-10 and 16 are pending in the instant application. Claims 1-6, 8-10 and 16 have been rejected. Claims 1, 2, 3, 4, 5, 8, 10 and 16 have been amended. Claim 6 has been canceled. Support for these amendments is provided in canceled claim 6 and in teachings in the specification at, for example, pages 391-395. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Objection to Specification

The specification has been objected to because not all trademarks are capitalized and/or accompanied by the generic terminology. Specifically, the Examiner has pointed to ISEE on page 401. However, the Examiner has requested Applicants to review the entire specification to ensure all trademarks are capitalized.

Accordingly, Applicants have reviewed and amended the specification to capitalize and/or include where necessary generic terminology for trademarks used in the application.

No new matter is added by this amendment and entry is respectfully requested.

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**II. Rejection of Claims 1-6, 8-10, 16 and 18 under 35 U.S.C. 112,
first paragraph - Enablement**

Claims 1-6, 8-10 and 16 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner has acknowledged the specification to be enabling for detecting risk or presence of colon cancer and lung cancer in a human patient. However, the Examiner suggests that the specification does not reasonably provide enablement for detecting risk or presence of these cancers in patients other than humans or for detecting risk or presence of cancers other than colon cancer or lung cancer, i.e. prostate cancer.

Applicants respectfully traverse this rejection.

At the outset, Applicants disagree with the Examiner's suggestion that the specification does not reasonably provide enablement for detecting risk or presence of cancers other than colon cancer or lung cancer in a human patient. Expression data on pages 391-395 of the instant application demonstrates that Cln224v1 expression is altered in cancer tissue compared to normal or normal adjacent tissue from a number of sites in human patients including colon, lung, breast, ovary, pancreas, small intestines, stomach and testes.

In an earnest effort to advance the prosecution of this case,

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Applicants have amended claim 1 to state that the nucleic acid is isolated from a human. Further, Applicants have amended claim 16 to state that the patient is a human patient and that the cancer is selected from the group comprising colon, lung, breast, ovarian, pancreatic, small intestine, stomach and testicular cancer.

The claims, as amended are clearly supported by teachings in the specification at pages 391-395 as well as claim 6, now canceled, thus meeting the enablement requirements of 35 U.S.C. 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

**III. Rejection of Claim 16 under 35 U.S.C. 112, first paragraph -
Written Description**

Claims 16 has been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the claim is drawn to a genus of kits comprising nucleic acid molecules that cancer be used for detecting risk or presence of cancer while the specification discloses only a species, namely a kit comprising the nucleotide sequence of SEQ ID NO:36 for diagnosis of colon cancer and lung cancer in a human patient.

Applicants respectfully traverse this rejection.

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At the outset, Applicants disagree with the Examiner's suggestion that the specification discloses only a species, namely a kit comprising the nucleotide sequence of SEQ ID NO:36 for diagnosis of colon cancer and lung cancer in a human patient. Expression data on pages 391-395 of the instant application demonstrates that Cln224v1 expression is altered in cancer tissue compared to normal or normal adjacent tissue from a number of sites in human patients including colon, lung, breast, ovary, pancreas, small intestines, stomach and testes.

In an earnest effort to advance the prosecution of this case, Applicants have amended claim 16 to state that the patient is a human patient and that the cancer is selected from the group comprising colon, lung, breast, ovarian, pancreatic, small intestine, stomach and testicular cancer.

Claim 16, as amended, is clearly supported by teachings in the specification at pages 391-395, thus meeting the written description requirements of 35 U.S.C. 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

IV. Rejection of Claims under 35 U.S.C. 102(b)

Claims 1-2, 4-6, 8-10 and 16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Oikawa et al. (Biochemical

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and Biophysical Research Communication, Vol. 142, Pages 511-518). The Examiner suggests that Oikawa et al. discloses a nucleic acid molecule, CEA, comprising a sequence that is about 80% identical to the sequence of SEQ ID NO:36 which would hybridize, at least in some portions, even under stringent hybridization and washing conditions to SEQ ID NO:36.

Accordingly, in an effort to advance the prosecution of this case, but without conceding to the correctness of the Examiner's assertion, Applicants have amended claim 1 to remove the language relating to hybridization.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

V. Rejection of Claims 1-6, 8-10 and 16-18 under 35 U.S.C. 102(f) and Obviousness-type Double Patenting

Claims 1-6, 8-10, 16 and 18 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-10, 16 and 18 of copending Application No. 10/558,861.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that the filing date for Application No. 10/558,861 is later than the instant application. Accordingly, as the term of the patent runs from the filing date

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of the application, it is Application No. 10/558,861 which may require a terminal disclaimer and/or claim amendment with respect to the instant application should there be overlapping claims. To date, Applicants have not received an Office Action in Application No. 10/558,861. Thus, amendments may be made to the claims in Application No. 10/558,861 which may eliminate any overlap in the claimed subject matter. Alternatively, Applicants may file a Terminal Disclaimer in Application No. 10/558,861 to address this issue.

Claims 1-6, 8-10 and 16-18 have also been rejected under 35 U.S.C. 102(f) over U.S. Patent Application Serial No. 10/558,861. SEQ ID NO:36 is suggested to be identical to SEQ ID NO:52 of U.S. Patent Application Serial No. 10/558,861. The Examiner has advised that rejection can be overcome by amendment of claims to be patentably distinct or by filing a Declaration that the inventive entity for the commonly claimed subject matter is identical.

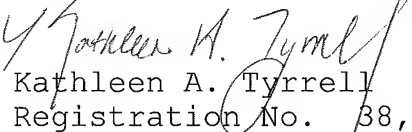
Applicants are submitting herewith a request and the requisite fee in accordance with 37 C.F.R. 1.48(b) that named inventor Albert Tam be deleted since the invention of Albert Tam is no longer claimed in the instant application. This request renders moot the rejection under 35 U.S.C. 102(f).

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Accordingly, withdrawal of these rejections over Application No. 10/558,861 is respectfully requested.

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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